Memo of Meeting

Date: July 26, 2001
1350 Piccard Drive, Rockville, MD 20850

Representing Datatrak International, Inc., Cleveland, Ohio
Mr. Jeffrey A. Green, President and CEO
Mr. Sudhir Achar, International Director, Quality Assurance
Dr. Jochen van Berkel, Ph.D., Director, Product Development

Representing the Food and Drug Administration:

Paul J. Motise, Consumer Safety Officer, Office of Enforcement
Tom Chin, Consumer Safety Officer, Office of Enforcement
Charles Snipes, Ph.D., Compliance Officer, Center For Drug Evaluation and Research
Tom Santucci, Computer Specialist, Office of Enforcement

The meeting was requested by the Datatrak International representatives, to discuss the firm's electronic records software. We explained at the outset that FDA does not formally review, approve or disapprove products and services that enable regulated establishments to comply with FDA requirements. We commented that our remarks should be taken in that context and that our meeting was more of an information exchange.

The Datatrak representatives explained that their firm is an application service provider in the electronic data capture (EDC) industry. The representatives gave us a brief overview of the firm's history – it started in 1993, took on the name EDS in 1995 and became Datatrak in 1998. The representatives claimed that their product has been implemented in more than 50 clinical trials in 31 countries involving thousands of sites; product use has reportedly demonstrated significant reductions in clinical trial duration, database efficiencies and improved data quality. Data entry for electronic case report forms is web based or on localized distributed platforms.

During the meeting the firm's representatives gave us a demonstration using wireless data entry equipment. This included a remote site in Germany. The representatives demonstrated how the system could use remote data entry to build and maintain clinical databases, and to troubleshoot investigator systems. Data does not reside on the input device, but goes directly to a CITRX based server. Datatrak offers the option of hosting the database itself at its Cleveland, Ohio facility. We commented that absence of clinical records at the clinical investigator was not in accord with current FDA regulations. We discussed the possibility of splitting the data stream so that clinical investigators retain the same files they recorded directly to the sponsors.

We discussed computer system validation and the firm's willingness to have its software development activities audited; the firm has experienced several such audits in the past 18 months.

The firm's representatives discussed some misconceptions about electronic data capture. They commented that, contrary to popular belief, EDC is not easily done by clinical investigators themselves. They noted that some people in industry erroneously believe that FDA does not accept EDC, and that some clinical investigators resist the technology.

The Datatrak representatives commented that EDC challenges include system performance, scalability, vendor viability, integrating with existing computing environments, and offering customers a flexible range of configurations from turn-key to add-on systems. They explained that they offer customers different purchase and operational options with respect to database hosting, training, and help desk facilities.

We discussed the system's audit trail function. The audit trail records the date and time (local) when electronic records are created, modified or deleted, the operator identification, prior values for changed items and the reason for making a change. The representatives commented that in at least one instance, an audit trail disclosed records falsification; a clinical investigator "appeared" to have examined the same patient during multiple visits over a time period of six minutes; in another instance, patient data were recorded a month after the patient visit.

When electronic records have been altered, the human readable form shows a flag to indicate that there had been a change.

During the meeting we also discussed long term archiving and the need to preserve the ability to process data that is migrated from one computer platform to another.

The meeting lasted about two hours.

cc:
HFA-224
FDA attendees
Part 11 Guidance Dockets
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